

Union Calendar No. 448

108TH CONGRESS
2^D SESSION

H. R. 3015

[Report No. 108-728]

To amend the Public Health Service Act to establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 4, 2003

Mr. WHITFIELD (for himself and Mr. PALLONE) introduced the following bill;
which was referred to the Committee on Energy and Commerce

OCTOBER 5, 2004

Additional sponsors: Mrs. NORTHUP, Mr. SESSIONS, Mr. STUPAK, Mrs. MALONEY, Mr. KLECZKA, Mr. DICKS, Mr. BROWN of Ohio, Mr. PASCRELL, Mr. LUCAS of Kentucky, Mr. GREEN of Texas, Mr. RAMSTAD, Mr. JEFFERSON, Mr. WEXLER, Mr. SANDLIN, Mr. NETHERCUTT, Mr. VITTER, Mrs. NAPOLITANO, Mr. WELDON of Florida, Mr. KILDEE, Mr. SOUDER, Mr. EMANUEL, Mr. BLUNT, Mr. FLETCHER, Ms. DELAURO, Mr. DEMINT, Mr. DAVIS of Illinois, Mrs. MUSGRAVE, Mr. BACHUS, Mrs. BONO, Mr. EVANS, Mr. SHAYS, Mrs. BIGGERT, Mr. SHIMKUS, Mr. BOOZMAN, Mr. PICKERING, Mr. HALL, Mr. PITTS, Ms. SCHAKOWSKY, Mrs. JOHNSON of Connecticut, Mr. BASS, Mr. FERGUSON, Mr. GILLMOR, Mr. JOHN, Mr. SULLIVAN, Mr. FORBES, Mr. WYNN, Mr. RUSH, Mrs. CHRISTENSEN, Mr. DEUTSCH, Mr. ENGEL, Mr. TERRY, Mr. HOEKSTRA, Mr. GONZALEZ, Mr. CHANDLER, and Mr. BROWN of South Carolina

OCTOBER 5, 2004

Reported with amendments, committed to the Committee of the Whole House
on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on September 4, 2003]

A BILL

To amend the Public Health Service Act to establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “National All Schedules*
5 *Prescription Electronic Reporting Act of 2004”.*

6 **SEC. 2. CONTROLLED SUBSTANCE MONITORING PROGRAM.**

7 *Part P of title III of the Public Health Service Act*
8 *(42 U.S.C. 280g et seq.) is amended by adding after section*
9 *399N the following:*

10 **“SEC. 399O. CONTROLLED SUBSTANCE MONITORING PRO-**
11 **GRAM.**

12 *“(a) FORMULA GRANTS.—*

13 *“(1) IN GENERAL.—Each fiscal year, the Sec-*
14 *retary shall make a payment to each State with an*
15 *application approved under this section for the pur-*
16 *pose of establishing and implementing a controlled*
17 *substance monitoring program under this section.*

1 “(2) *DETERMINATION OF AMOUNT.*—*In making*
2 *payments under paragraph (1) for a fiscal year, the*
3 *Secretary shall allocate to each State with an appli-*
4 *cation approved under this section an amount which*
5 *bears the same ratio to the amount appropriated to*
6 *carry out this section for that fiscal year as the num-*
7 *ber of pharmacies of the State bears to the number of*
8 *pharmacies of all States with applications approved*
9 *under this section (as determined by the Secretary),*
10 *except that the Secretary may adjust the amount allo-*
11 *cated to a State under this paragraph after taking*
12 *into consideration the budget cost estimate for the*
13 *State’s controlled substance monitoring program.*

14 “(b) *APPLICATION APPROVAL PROCESS.*—

15 “(1) *IN GENERAL.*—*To seek a grant under this*
16 *section, a State shall submit an application at such*
17 *time, in such manner, and containing such assur-*
18 *ances and information as the Secretary may reason-*
19 *ably require. Each such application shall include—*

20 “(A) *a budget cost estimate for the State’s*
21 *controlled substance monitoring program; and*

22 “(B) *assurances of compliance with the re-*
23 *quirements of this section.*

24 “(2) *APPROVAL OR DISAPPROVAL.*—*Not later*
25 *than 90 days after the submission by a State of an*

1 *application under paragraph (1), the Secretary shall*
2 *approve or disapprove the application. The Secretary*
3 *shall approve the application if the State dem-*
4 *onstrates to the Secretary that the State will establish*
5 *and implement a controlled substance monitoring*
6 *program in accordance with this section.*

7 “(3) *WITHDRAWAL OF AUTHORIZATION.—If a*
8 *State fails to implement a controlled substance moni-*
9 *toring program in accordance with this section—*

10 “(A) *the Secretary shall give notice of the*
11 *failure to the State; and*

12 “(B) *if the State fails to take corrective ac-*
13 *tion within a reasonable period of time, the Sec-*
14 *retary shall withdraw any approval of the*
15 *State’s application under this section.*

16 “(4) *VOLUNTARY DISCONTINUANCE.—A funding*
17 *agreement for the receipt of a payment under this sec-*
18 *tion is that the State involved will give a reasonable*
19 *period of notice to the Secretary before ceasing to im-*
20 *plement a controlled substance monitoring program*
21 *under this section. The Secretary shall determine the*
22 *period of notice that is reasonable for purposes of this*
23 *paragraph.*

24 “(5) *RETURN OF FUNDS.—If the Secretary with-*
25 *draws approval of a State’s application under this*

1 *section, or the State chooses to cease to implement a*
2 *controlled substance monitoring program under this*
3 *section, a funding agreement for the receipt of a pay-*
4 *ment under this section is that the State will return*
5 *to the Secretary an amount which bears the same*
6 *ratio to the overall payment as the remaining time*
7 *period for expending the payment bears to the overall*
8 *time period for expending the payment (as specified*
9 *by the Secretary at the time of the payment).*

10 *“(c) REPORTING REQUIREMENTS.—In implementing a*
11 *controlled substance monitoring program under this section,*
12 *a State shall comply with the following:*

13 *“(1) The State shall require dispensers to report*
14 *to such State each dispensing in the State of a con-*
15 *trolled substance to an ultimate user or research sub-*
16 *ject not later than 1 week after the date of such dis-*
17 *persing.*

18 *“(2) The State may exclude from the reporting*
19 *requirement of this subsection—*

20 *“(A) the direct application of a controlled*
21 *substance to the body of an ultimate user or re-*
22 *search subject;*

23 *“(B) the dispensing of a controlled sub-*
24 *stance in a quantity limited to an amount ade-*

1 *quate to treat the ultimate user or research sub-*
2 *ject involved for 48 hours or less; or*

3 *“(C) the application or dispensing of a con-*
4 *trolled substance in accordance with any other*
5 *exclusion identified by the Secretary for purposes*
6 *of this paragraph.*

7 *“(3) The information to be reported under this*
8 *subsection with respect to the dispensing of a con-*
9 *trolled substance shall include the following:*

10 *“(A) Drug Enforcement Administration*
11 *Registration Number of the dispenser.*

12 *“(B) Drug Enforcement Administration*
13 *Registration Number and name of the practi-*
14 *tioner who prescribed the drug.*

15 *“(C) Name, address, and telephone number*
16 *of the ultimate user or research subject.*

17 *“(D) Identification of the drug by a na-*
18 *tional drug code number.*

19 *“(E) Quantity dispensed.*

20 *“(F) Estimated number of days for which*
21 *such quantity should last.*

22 *“(G) Number of refills ordered.*

23 *“(H) Whether the drug was dispensed as a*
24 *refill of a prescription or as a first-time request.*

25 *“(I) Date of the dispensing.*

1 “(J) *Date of origin of the prescription.*

2 “(4) *The State shall specify an electronic format*
3 *for the reporting of information under this subsection*
4 *and may waive the requirement of such format with*
5 *respect to an individual dispenser.*

6 “(5) *The State shall automatically share infor-*
7 *mation reported under this subsection with another*
8 *State with an application approved under this sec-*
9 *tion if the information concerns—*

10 “(A) *the dispensing of a controlled sub-*
11 *stance to an ultimate consumer or research sub-*
12 *ject who resides in such other State; or*

13 “(B) *the dispensing of a controlled sub-*
14 *stance prescribed by a practitioner whose prin-*
15 *cipal place of business is located in such other*
16 *State.*

17 “(6) *The State shall notify the appropriate au-*
18 *thorities responsible for drug diversion investigation*
19 *if information in the database maintained by the*
20 *State under subsection (d) indicates a potential un-*
21 *lawful diversion or misuse of a controlled substance.*

22 “(d) *DATABASE.—In implementing a controlled sub-*
23 *stance monitoring program under this section, a State shall*
24 *comply with the following:*

1 “(1) *The State shall establish and maintain an*
2 *electronic database containing the information re-*
3 *ported to the State under subsection (c).*

4 “(2) *The database must be searchable by any*
5 *field or combination of fields.*

6 “(3) *The State shall include reported informa-*
7 *tion in the database at such time and in such manner*
8 *as the Secretary determines appropriate, with appro-*
9 *priate safeguards for ensuring the accuracy and com-*
10 *pleteness of the database.*

11 “(4) *The State shall take appropriate security*
12 *measures to protect the integrity of, and access to, the*
13 *database.*

14 “(e) *PROVISION OF INFORMATION.—Subject to sub-*
15 *section (f), in implementing a controlled substance moni-*
16 *toring program under this section, a State may provide in-*
17 *formation from the database established under subsection*
18 *(d) and, in the case of a request under paragraph (2) or*
19 *(3), compilations of such information, in response to a re-*
20 *quest by—*

21 “(1) *a practitioner (or the agent thereof) who*
22 *certifies that the requested information is for the pur-*
23 *pose of providing medical or pharmaceutical treat-*
24 *ment or evaluating the need for such treatment to a*
25 *bona fide current patient;*

1 “(2) any local, State, or Federal law enforce-
2 ment, narcotics control, licensure, disciplinary, or
3 program authority, who certifies that the requested
4 information is related to an individual investigation
5 or proceeding involving the unlawful diversion or
6 misuse of a schedule II, III, or IV substance, and such
7 information will further the purpose of the investiga-
8 tion or assist in the proceeding; or

9 “(3) any agent of the Department of Health and
10 Human Services, a State medicaid program, a State
11 health department, or the Drug Enforcement Adminis-
12 tration who certifies that the requested information is
13 necessary for research to be conducted by such depart-
14 ment, program, or administration, respectively, and
15 the intended purpose of the research is related to a
16 function committed to such department, program, or
17 administration by law that is not investigative in na-
18 ture.

19 “(f) *LIMITATIONS.*—In implementing a controlled sub-
20 stance monitoring program under this section, a State—

21 “(1) shall make reasonable efforts to limit the in-
22 formation provided pursuant to a valid request under
23 subsection (e) to the minimum necessary to accom-
24 plish the intended purpose of the request; and

1 “(2) shall not provide any individually identi-
2 fiable information in response to a request under sub-
3 section (e)(3).

4 “(g) RULES OF CONSTRUCTION.—

5 “(1) FUNCTIONS OTHERWISE AUTHORIZED BY
6 LAW.—Nothing in this section shall be construed to
7 restrict the ability of any authority, including any
8 local, State, or Federal law enforcement, narcotics
9 control, licensure, disciplinary, or program authority,
10 to perform functions otherwise authorized by law.

11 “(2) NO PREEMPTION.—Nothing in this section
12 shall be construed as preempting any State law, ex-
13 cept that no such law may relieve any person of a re-
14 quirement otherwise applicable under this Act.

15 “(3) NO FEDERAL PRIVATE CAUSE OF ACTION.—
16 Nothing in this section shall be construed to create a
17 Federal private cause of action.

18 “(h) RELATION TO HIPAA.—Except to the extent in-
19 consistent with this section, the provision of information
20 pursuant to subsection (c)(5), (c)(6), or (e) and the subse-
21 quent transfer of such information are subject to any re-
22 quirement that would otherwise apply under the regulations
23 promulgated pursuant to section 264(c) of the Health Insur-
24 ance Portability and Accountability Act of 1996.

1 “(i) *PREFERENCE.*—*The Secretary, in awarding any*
2 *competitive grant that is related to drug abuse (as deter-*
3 *mined by the Secretary) to a State, shall give preference*
4 *to any State with an application approved under this sec-*
5 *tion.*

6 “(j) *STUDY.*—*Not later than 1 year after the date of*
7 *the enactment of this section, the Secretary shall—*

8 “(1) *complete a study on—*

9 “(A) *the progress of States in establishing*
10 *and implementing controlled substance moni-*
11 *toring programs under this section; and*

12 “(B) *the feasibility of implementing a real-*
13 *time electronic controlled substance monitoring*
14 *program, including the costs associated with es-*
15 *tablishing such a program; and*

16 “(2) *submit a report to the Congress on the re-*
17 *sults of the study.*

18 “(k) *ADVISORY COUNCIL.*—

19 “(1) *ESTABLISHMENT.*—*A State may establish*
20 *an advisory council to assist in the establishment and*
21 *implementation of a controlled substance monitoring*
22 *program under this section.*

23 “(2) *SENSE OF CONGRESS.*—*It is the sense of the*
24 *Congress that, in establishing an advisory council*
25 *under this subsection, a State should consult with*

1 *State boards of pharmacy, State boards of medicine,*
2 *and other interested parties.*

3 “(l) *DEFINITIONS.—For purposes of this section:*

4 “(1) *The term ‘bona fide patient’ means an indi-*
5 *vidual who is a patient of the dispenser or practi-*
6 *tioner involved.*

7 “(2) *The term ‘controlled substance’ means a*
8 *drug that is—*

9 “(A) *included in schedule II, III, or IV of*
10 *section 202(c) of the Controlled Substance Act; or*

11 “(B) *identified by the State involved as a*
12 *drug subject to the monitoring program of the*
13 *State under this section.*

14 “(3) *The term ‘dispense’ means to deliver a con-*
15 *trolled substance to an ultimate user or research sub-*
16 *ject by, or pursuant to the lawful order of, a practi-*
17 *tioner, irrespective of whether the dispenser uses the*
18 *Internet or other means to effect such delivery.*

19 “(4) *The term ‘dispenser’ means a physician,*
20 *pharmacist, or other individual who dispenses a con-*
21 *trolled substance to an ultimate user or research sub-*
22 *ject.*

23 “(5) *The term ‘practitioner’ means a physician,*
24 *dentist, veterinarian, scientific investigator, phar-*
25 *macy, hospital, or other person licensed, registered, or*

1 *otherwise permitted, by the United States or the juris-*
2 *diction in which he or she practices or does research,*
3 *to distribute, dispense, conduct research with respect*
4 *to, administer, or use in teaching or chemical anal-*
5 *ysis, a controlled substance in the course of profes-*
6 *sional practice or research.*

7 “(6) The term ‘State’ means each of the 50
8 *States and the District of Columbia.*

9 “(7) The term ‘ultimate user’ means a person
10 *who has lawfully obtained, and who possesses, a con-*
11 *trolled substance for his or her own use, for the use*
12 *of a member of his or her household, or for the use*
13 *of an animal owned by him or her or by a member*
14 *of his or her household.*

15 “(m) *AUTHORIZATION OF APPROPRIATIONS.—To*
16 *carry out this section, there are authorized to be appro-*
17 *priated—*

18 “(1) \$25,000,000 for each of fiscal years 2006
19 *and 2007; and*

20 “(2) \$15,000,000 for each of fiscal years 2008,
21 *2009, and 2010.”.*

Amend the title so as to read: “A bill to provide for
the establishment of a controlled substance monitoring
program in each State.”.

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[Report No. 108-728]

A BILL

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OCTOBER 5, 2004

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed